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EXAMINER

BEHRINGER, LUTHER G

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4148

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,601	Applicant(s) PETERS ET AL.	
	Examiner LUTHER G. BEHRINGER	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 8, 24 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to application no. 10/595601 filed on 04/28/2006.

Claim Objections

2. Claim(s) 2, 3, 24 and 36 are objected to because of the following informalities:

Claim 2 refers to a wave, "combination wave detection," but fails to indicate the type of wave, e.g. an R-wave or an arterial pressure wave, as disclosed in the specification.

3. In **claim 3**, it appears that a reference character is missing from the following phrase: "by utilizing both the and S2 sounds". For examination purposes, the examiner is assuming that the missing reference character is "S1" as shown in the original claims.

4. In **claim 8**, the claim states that it is dependent on itself.

5. In **claim 24**, it appears that the word salable is misspelled.

6. On the fifth line of **claim 36** the following phrase appears incorrect: "a sound signal indicative of heart sounds S 1 S2 through PCG channel".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim(s) 1 – 5, 7 – 11, 13 – 17, 25, 26, 28, 30, 31 and 33 – 36 are rejected under 35 U.S.C. 102(e) as being anticipated by **Mai et al. (US 6,643,548, herein Mai)**.

Regarding **claim 1**, Mai discloses a method of controlling the operation of a pulsatile heart assist device in a patient, consisting of utilizing sounds produced by the heart to control the operation of the heart assist device (Col. 2, Lines 19 - 29 and Lines 56 - 63).

Regarding **claim 2**, Mai discloses wherein the method uses a combination wave detection and heart sound detection to control the operation of the heart assist device (Col. 2, Lines 19 - 29 and Lines 56 - 63).

Regarding **claim 3**, Mai does not explicitly disclose wherein the heart assist device is completely controlled by utilizing both the (S1) and S2 sounds of the heart to both stop and start the heart assist device but does disclose these limitations in combination with detecting electronic heart waves thus illustrating that the technique is known (Col. 2, Lines 19 - 29 and Lines 56 - 63).

Regarding **claim 4**, Mai discloses a method of controlling the operation of a pulsatile heart assist device in a patient, consisting of electrically detecting the R-wave of the patient's heart rhythm and producing a signal to initiate a change in the pulsatile status of the heart assist device, and detecting a sound or pressure wave created by the closure of the patient's aortic valve and producing a signal to return the heart assist

device to the pulsatile status it had before the preceding R-wave (Col. 2, Lines 30 - 34 and Lines 56 - 63).

Regarding **claim 5**, Mai discloses a method of controlling the operation of a pulsatile heart assist device with a multi-channel digital signal processor and transmitter (DSPT), **60**, the DSPT being of the type having an ECG channel, *data acquisition channel* **90**, and a phonocardiographic (PCG), **110**, the DSPT being at least adapted to normally sense an electrical signal, *cardiac signal*, indicative of cardiac rhythm, *electrogram (EGM)*, through the ECG channel, and to normally sense heart sounds through the PCG channel, **110**, and to transmit signals, **104**, to an external receiver, **102**, the method comprising the steps operatively connecting the DSPT bipolar ECG lead, **24 and 32**, to a patient's heart, **12**; and operatively connecting the DSPT microphone, **110**, to the patient's heart, *via sound conducting leads*, whereby, after detecting an R-wave via the ECG channel, the DSPT issues a R- wave signal to the heart assist device controller to control the timing of the pulsation of the heart assist device, and whereby, after detecting a heart sound via the PCG channel, the DSPT issues a heart sound signal to the heart assist device controller to control the timing of the pulsation of the heart assist device (Fig. 1, Col. 6, Lines 17 - 23; Col. 7, Lines 28 - 41; Col. 11, Lines 1 - 12).

Regarding **claim 7**, Mai discloses wherein the DSPT is able to receive as well as transmit, **104** (Fig. 1).

Regarding **claim 8**, Mai discloses wherein the DSPT has parameter settings adjusted within ranges, for detecting the R-wave and the heart sounds, and for the output signals, automatically adjust pacing therapy responsive to the physiological parameter measurements (Col. 11, Lines 1 - 12).

Regarding **claim 9**, Mai discloses wherein the ECG lead, **24 and 23**, connected to the patient's heart, **12**, is epicardial or endocardial or attached to an implanted heart assist device itself (Fig. 1).

Regarding **claim 10**, Mai discloses wherein sensors for the collection of an ECG signal are embedded into the surface of a heart assist device applied to the heart or another part of the patient's body from which an ECG signal may be received (Fig. 1).

Regarding **claim 11**, Mai discloses wherein the DSPT microphone, **110**, is internal to the patient's body (Fig. 1; Col. 3, Lines 30 - 32).

Regarding **claim 13**, Mai discloses wherein the connection to the patient's heart is endocardial (Fig. 1; Col. 3, Lines 30 - 32).

Regarding **claim 14**, Mai discloses wherein the connection to the patient's heart is in the manner of a pacing lead, 20 or 30 (Fig. 1; Col. 3, Lines 30 - 32).

Regarding **claim 15**, Mai discloses wherein the connection to the patient's heart is attached to the implanted device itself (Fig. 1; Col. 3, Lines 30 - 32).

Regarding **claim 16**, Mai does not explicitly disclose wherein the connection to the patient's heart is located within 50 mm of the cardiac valves. Mai does disclose

placing pacing leads in multiple locations within the heart (Col. 3, Lines 59 – 67). As is well known by one having ordinary skill in the art, solid materials are excellent conductors of sound, and pacing leads have solid conductors within them. As a result, placing a pacing lead in the heart with a solid conductor connected to the implantable medical device of Mai which contains a microphone, **110**, would inherently place a microphone into the heart, **12** (Fig. 1).

Regarding **claim 17**, Mai does not explicitly disclose wherein the connection to the patient's heart is without the lung between the microphone and the patients heart. Mai does disclose placing pacing leads in multiple locations within the heart (Col. 3, Lines 59 – 67). As is well known by one having ordinary skill in the art, solid materials are excellent conductors of sound, and pacing leads have solid conductors within them. As a result, placing a pacing lead in the heart with a solid conductor connected to the implantable medical device of Mai which contains a microphone, **110**, would inherently place a microphone into the heart, **12** (Fig. 1).

Regarding **claim 25**, Mai discloses wherein the DSPT is able to receive signals, **104**, from an external device to adjust digital signal processing variables within the DSPT for detecting and heart sounds (Fig. 1).

Regarding **claim 26**, Mai discloses wherein the DSPT has a battery of sufficient life that the DSPT can be removed and replaced, independent of the cardiac sensing leads (Col. 6, Lines 51 – 53).

Regarding **claim 28**, Mai discloses wherein the DSPT can communicate directly with an implanted controller (Col. 5, Lines 58 - 63).

Regarding **claim 30**, Mai discloses a dual channel DSPT, **60**, configured for use in controlling the operation of a pulsatile heart assist device, the DSPT being of the type having an ECG channel, *data acquisition channel 90*, and a phonocardiographic (PCG) channel, **110**, the DSPT being at least adapted to normally sense an electrical signal, *cardiac signal*, indicative of cardiac rhythm through the ECG channel, and to normally sense heart sounds through the PCG channel, and to transmit signals to an external receiver, *a diagnostic system analyzer*, to control the timing of the pulsation of the heart assist device (Fig. 1, Col. 5, Lines 58 - 63; Col. 6, Lines 17 - 23; Col. 11, Lines 1 - 12).

Regarding **claim 31**, Mai discloses wherein signals, **104**, are directly sent to an implanted controller (Fig. 1, Col. 5, Lines 58 - 63).

Regarding **claim 33**, Mai discloses wherein the DSPT is able to receive as well as transmit (Fig. 1, Col. 5, Lines 58 - 63).

Regarding **claim 34**, Mai discloses wherein the DSPT has parameter settings adjustable within ranges, for detecting the R-wave and the Heart Sounds, and for the output signals (Col. 11, Lines 1 - 12).

Regarding **claim 35**, Mai discloses wherein the DSPT has other channels for detecting aortic and left ventricular blood pressure and for movement of the aortic or ventricular walls, and signals from these channels can also be interpreted to control heart assist device functioning (Col. 5, Lines 58 - 63).

Regarding **claim 36**, Mai discloses means for controlling a co-pulsation or counter-pulsation heart assist device, the means including: a co- or counter-pulsation heart assist device, **10**; a controller, **60**, for the heart assist device; and a DSPT of the type at least adapted to normally sense an electrical signal indicative of cardiac rhythm through an ECG channel, *cardiac signal*, and a sound signal indicative of heart sounds S1 S2 through a PCG channel, **110**, and to issue identifiable signals to the controller, in which the DSPT is set to issue pacing signals from the ventricular circuit at a minimum rate which is below a sensible rate in the event that the atrial circuit is unable to sense a rhythm signal from the patient's ventricle, and the controller is set to turn off the heart assist device in the event that the pacing signals that the controller receives from the DSPT are at a rate below a predetermined rate which is above the minimum rate (Fig. 1; Col. 11, Lines 1 – 12).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim(s) 6 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Jones et al. "Acoustic Characterization of Thoracic Body Tissues in the Audible Frequency Range." Journal of Biological Physics. Vol 21, Number 2. 1995.**

Regarding **claim(s) 6 and 32**, Mai fails to disclose wherein the DSPT is adapted to normally sense heart sounds through the PCG channel in the range of 20- 500 Hz.

However, Jones teaches the frequency dependence of the acoustic attenuation and speed of propagation through thoracic tissue samples in the audible frequency range 20–500 Hz (Abstract).

12. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai with the teachings of Jones et al. to ensure accurate and reliable acquisition of phonocardiogram readings which can aid in the pulsatile treatment of heart disorders.

13. Claim 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Larson, Jr. et al. (US 5,722,930, herein Larson)**.

Regarding **claim 12**, Mai fails to disclose wherein the connection to the patient's heart is epicardial.

However, Larson teaches a pair of epicardial sensing leads.

14. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of the flexibility of utilizing an epicardial connection to achieve reliable ECG readings. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Mai to include epicardial sensing leads as taught by Larson, as it is a well known method of acquiring an ECG signal from a patient's heart.

Regarding **claim 29**, Mai discloses wherein the controller and the ECG and microphone are contained together, but fails to disclose them being within the pump and the pump positioned in the medial right chest, with one aspect of the pump (containing hermetically sealed microphone and ECG electrodes) against the right heart structures.

However, Larson teaches the use of an implantable pump, **34**, positioned in the medial right chest (Fig. 11).

15. Since the marketplace reflects the reality that applying modern, more compact electronics to older implantable electronic devices is commonplace and it is commonly understood within the art to reduce implantable devices where possible, it would have been obvious to one of ordinary skill in the art of electrical medicinal therapy at the time of the invention to update the device of Mai by combining the electronics shown in Mai with the pump shown in Larson using modern more compact electronics that are commonly available and understood in the art in order to gain the commonly understood benefits of such adaptation, such as increased reliability, reduced size, simplified

operation, reduced cost and reduced risk associated to the patient due to more lengthy surgery necessary to implant additional devices.

16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Luisada et al. On the Function of the Aortic Valve and the Mechanism of the First and Second Sounds. Japanese Heart Journal. Vol. 18(1), Jan 1977. pp. 81-91.**

Regarding **claim 18**, Mai fails to disclose wherein the microphone is positioned outside the body of the patient.

However, **Luisada et al.** teaches wherein the microphone is positioned outside the body of the patient (Page 82, fourth paragraph).

17. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai to incorporate the teachings of Luisada to provide a microphone positioned outside the body of a patient, as this will provide for a reliable acoustic reading of the heart.

18. Claim(s) 19 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Luisada et al. On the Function of the Aortic Valve and the Mechanism of the First and Second Sounds. Japanese Heart Journal. Vol. 18(1), Jan 1977. pp. 81-91** as applied to Claim 18 and further in view of **Pizon et al. (US 4,459,977, herein Pizon)** further in view of **Reeves (US 5,337,752).**

Regarding **claim 19**, Mai in view of Luisada et al. discloses wherein the heart sounds and ECG are controlling, as stated above, but fail to disclose an external gas-driven extra-aortic balloon pump using an external microphone placed in the lumen of the extra aortic balloon or the gas line leading to the extra aortic balloon.

However, Pizon teaches the use of an external gas-driven extra-aortic balloon pump (Abstract, Fig. 1).

19. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai in view of Luisada et al. with the teachings of Pizon since external gas-driven aortic balloon pumps are a well known, reliable technology within the art.

Mai in view of Luisada et al. in view of Pizon fails to disclose using an external microphone placed in the lumen of the extra aortic balloon or the gas line leading to the extra aortic balloon.

However, Reeves teaches using an external microphone placed in the lumen of the extra aortic balloon or the gas line leading to the extra aortic balloon (Col. 5, Lines 31 – 42).

20. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai in view of Luisada et al. in view of Pizon with the teachings of Reeves to provide for an accurate, reliable acquisition of the heart sounds for cardiac rhythm therapy.

Regarding **claim 20**, Mai in view of Luisada et al. in view of Pizon in view of Reeves disclose wherein the implanted gas line and balloon acts as a 'stethoscope,'

and heart sounds can be detected intermittently or continuously, and sent directly to a controller, *a diagnostic system analyzer*, positioned outside the patient's body (Mai: Col. 5, Lines 58 – 63).

A stethoscope acts as a means to conduct sound from the patient's body to the medical practitioner. As is well known by one having ordinary skill in the art, solid materials are excellent conductors of sound, and the implanted gas line has solid conductors within it.

21. Claim(s) 21 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Luisada et al. On the Function of the Aortic Valve and the Mechanism of the First and Second Sounds. Japanese Heart Journal. Vol. 18(1), Jan 1977. pp. 81-91** in view of **Pizon et al. (US 4,459,977, herein Pizon)** in view of **Reeves (US 5,337,752)** as applied to Claim 20, further in view of **Meadows et al. (US 6,553,263, herein Meadows)**.

Regarding **claim 21**, Mai in view of Luisada et al. in view of Pizon in view of Reeves fails to disclose wherein a percutaneous ECG lead is used to directly transmit the ECG signal to the controller.

However, Meadows teaches the use of percutaneous extensions, **132**, capable of being used as a percutaneous ECG lead to directly transmit the ECG signal to the controller, **140** (Fig. 2).

22. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai in view of Luisada et al. in view of Pizon

in view of Reeves with the teachings of Meadows to provide a percutaneous connection to be used to directly transmit the ECG signal to the controller since percutaneous connections are a well known, reliable means of transmitting data.

Regarding **claim 22**, Mai in view of Luisada et al. in view of Pizon in view of Reeves fails to disclose wherein the ECG lead is combined with the percutaneous gas line.

However, Meadows teaches the use of percutaneous extensions, **132**, capable of performing the function of an ECG lead and Pizon teaches a percutaneous gas line (Fig. 2). All of the component parts are known in Meadows and Pizon. The only difference is the combination of the “old elements” into a single device by mounting them onto a single percutaneous line/lead.

23. Thus, it would have been obvious to one having ordinary skill in the art to mount the percutaneous gas line taught by Pizon and the percutaneous extensions taught by Meadows onto a single lead since the operation of the respective parts are in no way dependent on each other and a percutaneous gas line could be used in combination with percutaneous extensions to achieve the predictable results of reduced chance of infection during operation of a heart assist device.

Regarding **claim 23**, Mai in view of Luisada et al. in view of Pizon in view of Reeves wherein the ECG lead is separate from the percutaneous gas line.

However, Meadows teaches the use of percutaneous extensions, **132**, capable of being used as a percutaneous ECG lead (Fig. 2).

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24. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai in view of Luisada et al. in view of Pizon in view of Reeves since Mai discloses leads, **20 and 30** (Mai: Fig. 1) to provide data to the device. Using the known technique of percutaneous connections to an implantable medical device to provide data to the device as shown in Meadows would have been obvious to one of ordinary skill.

25. Claim(s) 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mai et al. (US 6,643,548, herein Mai)** in view of **Luisada et al. On the Function of the Aortic Valve and the Mechanism of the First and Second Sounds. Japanese Heart Journal. Vol. 18(1), Jan 1977. pp. 81-91** in view of **Pizon et al. (US 4,459,977, herein Pizon)** in view of **Reeves (US 5,337,752)** in view of **Meadows et al. (US 6,553,263, herein Meadows)** as applied to Claim 22, further in view of **Freed et al. (WO 98/51367, herein Freed)**.

Regarding **claim 24**, Mai in view of Luisada et al. in view of Pizon in view of Reeves in view of Meadows fails to disclose further including a releasable and s(e)alable connection for the percutaneous gas line and the ECG lead under the skin.

However, Freed teaches a releasable and s(e)alable connection for the percutaneous gas line and the ECG under the skin (Abstract).

26. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of a releasable and s(e)alable connection for the percutaneous gas line and the ECG under the skin to achieve connectivity to a control

unit. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Mai in view of Luisada et al. in view of Pizon in view of Reeves in view of Meadows to include a releasable and s(e)alable connection for the percutaneous gas line and the ECG under the skin as taught by Freed, allowing quick and reliable interchangeability of the external device without the need for additional subcutaneous tunneling necessary for additional percutaneous leads.

27. Claim 27 is rejected under 35 U.S.C. 103(a) as being obvious over **Mai et al. (US 6,643,548, herein Mai)** in view of **Meadows et al. (US 6,553,263, herein Meadows)**.

Regarding **claim 27**, Mai fails to disclose wherein the DSPT has a rechargeable battery that can be recharged by induction, or Transcutaneous Energy Transfer (TET).

However, Meadows teaches wherein the DSPT has a rechargeable battery that can be recharged by induction, or Transcutaneous Energy Transfer (TET) (Abstract).

28. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Mai to incorporate the teachings of Meadows concerning rechargeable batteries to prolong the reliable operation of the implantable medical device. Using the known technique of battery recharging within an implantable medical device to provide power to the device as shown in Meadows would have been obvious to one of ordinary skill.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Lewkowicz; Shlomo (US 4,594,731)**, **Kieval; Robert S. et al.**

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(US 5,554,177), Hastings; Roger N. et al. (US 6,251,061), Jansen; Jozef Reinier Cornelis et al. (US 7,169,109).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Luther Behringer
February 26, 2008

/Terrell L McKinnon/ Supervisory Patent Examiner, Art Unit 4148

